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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,618	02/15/2001	Eberhard Amtmann	8654/2002	2652
29933	7590	03/22/2004	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/784,618

Applicant(s)

AMTMANN ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The finality of the Office Action of 10/6/03 is withdrawn in view of the following rejections.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers disclosed on page 25, lines 2-3, does not reasonably provide enablement for any and all cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.

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7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to a method of treating cancer.

2) State of the prior art.

The references do not indicate which cancers may be treated by the compounds of Formula I. Additionally, the Applicants have argued in the Paper of 7/14/03 that since the only complexes listed in the Craciunescu reference and potentially falling within the definition of formula (I) of the present patent application are not listed in Table II of the Craciunescu reference and it states in the reference that complexes not listed in Table II were found to be inactive with all tumor types, no compositions were produced in the Craciunescu reference containing a complex according to formula (I) of the present patent application.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Applicant's specification does not enable one to use the instant composition to treat all cancers.

4) Level of predictability in the art.

The art pertaining to the treatment of cancer is unpredictable. There is no one compound that is useful to treat all cancers. There would be little predictability in using the instant composition to treat all cancers.

5) Amount of direction and guidance provided by the inventor.

Cancers encompass a broad variety of proliferative conditions that are treated with different compounds. It would require undue experimentation to determine which cancers could be treated with the compound of Formula I.

6) Existence of working examples.

Applicant's working examples do not enable the public to use the compound of Formula I to treat any and all cancers. The specification provides data only a limited number of cancers.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible cancers that may be treated.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. It would require undue experimentation to determine which cancers could be treated with the compound of Formula I.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

Amending the independent claim to recite the cancer of claims 13 and 15 would overcome this rejection.

Claim 12-13, 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12 the phrase "cancerous disease" is confusing as to whether the recipient has more than one cancerous disease. Amending the phrase to recite "a cancerous disease" will overcome this rejection.

In claim 12 the word "general" in the phrase "general formula (I)" is confusing as to whether other variants are intended to be included. Amending the claim to delete "general" will overcome this rejection.

In claim 12, line 8 of the text, the punctuation renders the claim unclear, since a claim can have a period only at the end of the claim.

In claim 12 there is no antecedent basis for the phrase "said compounds."

It is not clear that the intended recipient is in need of the intended method. Amending the claim to recite "A method of treating a cancer selected from the group consisting of ...in a human being or a mammal in need thereof...comprising administering to said human being or mammal a pharmaceutical preparation comprising a compound of formula I in an amount effective to treat said cancer.

In claim 15 the use of the plural is confusing as to what kinds of cancer are being claimed, since it is not clear that there is more than one kind of testicular cancer,

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ovarian carcinoma, melanoma etc. Amending the claim to recite each cancer in the singular will overcome this rejection.

In claim 16 the intent of the phrase "residue each" is unclear. Amending the claim to recite "...R<sub>1</sub> and R<sub>2</sub> are each a ...residue" will overcome this rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 16-19 rejected under 35 U.S.C. 102(are) as being anticipated by CA107:108004 (Osa). Osa (abstract) discloses the instant when compound R<sub>1</sub> and R<sub>2</sub> are each ethyl and that it has high antitumor activity. Claims 13 and 19 appear to differ over Osa in reciting a pharmaceutical composition and a compatible inert carrier or diluent. However, it would be inherent that the compound of Osa was administered as a composition, since it would have been administered as a solution.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA107:108004 (Osa) in view of MEDLINE AN 96354887 (Shibusawa) or MEDLINE AN 1998252553 (Weisman) or MEDLINE AN 1998277308 (Tessier) and MEDLINE AN 90112359 (Hollis).

Osa (abstract) discloses the instant compound when compound R<sub>1</sub> and R<sub>2</sub> are each ethyl and that it has high antitumor activity against Sarcoma 180 ascites. Claims 13 and 19 appear to differ over Osa in reciting a pharmaceutical composition and a compatible inert carrier or diluent. However, it would be obvious to one of ordinary skill in the art that the compound of Osa was administered as a composition, since it would have been administered as a solution.

Claims 13 and 15 differ over Osa in reciting specific tumors. However, Shibusawa (abstract), Weisman (abstract) and Tessier (abstract) disclose that the platinum compound cisplatin is useful to treat colorectal carcinoma, squamous cell cancer of the head and neck and melanoma, respectively. Furthermore, Hollis (abstract) discloses that cisplatin has antitumor activity against Sarcoma 180 ascites. It would be obvious to one of ordinary skill in the art that the instant compound would be effective in treating the tumors of claims 13 and 15, since both it and cisplatin are effective against Sarcoma 180 ascites and cisplatin is taught to be useful to treat the recited tumors of claims 13 and 15. One would be motivated to use the instant compound when the side effect profile of cisplatin is too toxic or the cancer becomes resistant to it, since both are common in the cancer treatment art.



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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 272-0584.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Pettus (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', with a stylized, cursive script.

Primary Examiner  
Art Unit 1614

March 18, 2004